STERILIZATION: PRINCIPLES AND VALIDATION
ASEPTIC PROCESSING: COMPLIANCE AND TECHNOLOGY
Take Either Course or Save on Both

SEPTEMBER 23-27, 2019, PRINCETON, NEW JERSEY

Course Descriptions

**Sterilization: Principles & Validation** – Monday – Wednesday (9/23-25)
The sterilization course covers the entire range of sterilization processes utilized in the pharmaceutical, biotechnology and medical device industries. Sterilization methods, validation practices and related subjects to be covered include: Prerequisites for Sterilization; Microbiology of Sterilization; Use of Biological Indicators; Steam Sterilization for Porous Loads; Terminal Sterilization using Steam; Steam Sterilization-in-Place; Dry Heat Sterilization and Depyrogenation; Gas, Liquid and Vapor Sterilization (including isolator decontamination); Radiation Sterilization; Filtration Sterilization for Liquids; Compendial and Regulatory Considerations.

**Aseptic Processing: Compliance & Technology** – Thursday – Friday (9/26-27)
The aseptic course will provide comprehensive coverage of aseptic processing reviewing basic principles, technology choices, process design, environmental monitoring, and process simulation. The course will include sessions on aseptic processing risk assessment, contemporary regulatory expectations and future technologies process. The course materials and recommendations are wholly compatible with the regulatory expectations of FDA’s 2004 Guideline on Sterile Drug Products Produced by Aseptic Processing and EMA’s – Annex 1 on Sterile Medicinal Products.

Who Should Attend
These courses are intended for individuals working with sterilization, aseptic processing or process validation. Experienced individuals will refine their knowledge through interaction with industry experts. Those without a strong background will learn the basics and develop an understanding of the more advanced considerations. The courses are appropriate for personnel working in QA/QC, regulatory affairs, R&D, production, engineering, process development, validation, and microbiology.

Testimonials from Prior Attendees
“Great course for any level of experience”
“… packed with useful information to help me build a foundation of sterilization fundamentals”
“A must for everyone interested in aseptic processing”
“Course was very insightful and practical”
“Best course I’ve attended. Loved the level of detail”
Course Location

Princeton, New Jersey
The courses will be held at the Chauncey Conference Center, 1½ miles from Princeton, NJ. Princeton is midway between the Newark, NJ and Philadelphia, PA airports. The hotel provides free shuttle service to/from the center of Princeton. Room reservations should be made directly with the hotel. The Chauncey Conference center can be reached at (609) 921-3600 or on line at http://www.acc-chaunceyconferencecenter.com.

Discounts
Early registration must be received not less than 45 days (August 9th) prior to the start of the course in the form of full payment or purchase order. Group discounts are offered on each registration when 3 or more registrants from the same company attend the same course. Early registration and group discounts will be combined for greater savings.

Credit Cards
Sorry but we do not accept credit cards for payment. Purchase order or check payments only.

Cancellations
Course fees are fully refundable, if written notice is received 14 days prior to the start of each course. Within 14 days, your fee will be refunded less a $250 per day service fee.

Confirmation
Electronic confirmation of registration will be sent once payment has been received.

Substitutions
Substitutions are welcome without prior notice

Accommodations
Transportation, accommodation and other expenses are the responsibility of the attendee. We do not book accommodations for attendees. The Princeton venue has on-site hotel rooms. There are numerous additional hotels within a 10-15 mile radius to choose from as well.

Vegetarian Meals
These are available each day without prior notification.
James Agalloco is President of Agalloco & Associates, which provides a range of technical services to the pharmaceutical and biotechnology industry. Since the formation of A&A in 1991, Jim has assisted more than 200 pharmaceutical, biotechnology, medical device, equipment manufacturers and bulk pharmaceutical firms in a range of validation, sterilization, aseptic processing and compliance areas. Jim has more than 45 years of industrial experience. He was previously employed at Bristol-Myers Squibb, Pfizer and Merck. He has a BE and MS in Chemical Engineering and an MBA in Pharmaceutical Studies.

Jim is a past President of the Parenteral Drug Association and served as an Officer or Director from 1982 to 1993. He is a current member of USP’s Microbiology Expert Committee. He serves on the Editorial Advisory Boards of *Pharmaceutical Technology* and *Pharmaceutical Manufacturing*. Jim participates on the Scientific Advisory Boards of; MEDInstill and Eniware.

He has authored or co-authored more than 40 book chapters, over 140 papers and has lectured extensively on process validation, aseptic processing, and sterilization. He is co-editor of “Validation of Pharmaceutical Processes”, 3rd edition and “Advanced Aseptic Processing Technology.”

Russell Madsen is President of The Williamsburg Group, engaged in pharmaceutical consulting in the areas of CGMP compliance and auditing, quality systems, design review, aseptic processing and sterilization technology, sterile filtration, due diligence evaluation, process validation, and regulatory liaison. Russ has over 45 years of experience in the pharmaceutical and related industries, including pharmaceutical manufacturing and quality control, medical devices, nutritional products, and consumer products. He has a B.S. and M.S. in Chemistry.

Prior to establishing TWG, Russ was employed by PDA, Bristol-Myers Squibb, Sterling Drug and Winthrop Laboratories. He is Vice-Chairman of ASTM Committee E55, a member of the USP Microbiology Expert Committee, Chairman of the USP Visual Inspection of Parenterals Expert Panel, a member of Pharmaceutical Technology’s Editorial Advisory Board, and an Honorary Member of PDA. He has published more than fifty scientific papers, books and book chapters and is co-editor of “Contamination Control in Healthcare Product Manufacturing.”
## Sterilization: Principles & Validation Schedule

### Day 1 – Monday – 9/23

8:00 - 8:30 AM  
Registration for Sterilization & Combined Morning Coffee  

8:30 - 10:00 AM - Session 1  
Welcome / Introductions  
Prerequisites for Sterilization Validation  
Microbiology of Sterilization  

10:00 - 10:15 AM - Break  

10:15 AM - 12:15 PM - Session 2  
Biological Indicators Preparation & Use  
Steam Sterilization Fundamentals  

12:15 PM - 1:15 PM - Lunch  

1:15 - 3:00 PM - Session 3  
Parts Sterilization  

3:00 - 3:15 PM - Break  

3:15 - 4:45 PM - Session 4  
Terminal Sterilization by Moist Heat  
Equivalence in Sterilization  

### Day 2 (continued)

12:15 PM - 1:15 PM - Lunch  

1:15 - 3:00 PM - Session 7  
Gas Sterilization  
Liquid Sterilization  
Vapor Sterilization  

3:00 - 3:15 PM - Break  

3:15 - 4:45 PM - Session 8  
Radiation Sterlingization  
New Sterilization Methods  

### Day 2 – Tuesday – 9/24

8:00 - 8:30 AM  
Morning Coffee  

8:30 - 10:15 AM - Session 5  
Sterilization-in-Place  
Bulk Liquid Sterilization  

10:15 - 10:30 AM - Break  

10:30 - 12:15 AM - Session 10  
Sterilizing Filtration – Application & Operation  

12:15 – 1:15 PM - Lunch  

1:15 - 3:00 PM - Session 11  
US Regulatory & Compendial Expectations  

3:00 - 3:15 PM - Break  

3:15 - 4:45 PM - Session 12  
EU Regulatory & Compendial Expectations  

4:45 PM – Sterilization Course Ends  

### Day 3 – Wednesday – 9/25

8:00 - 8:30 AM  
Morning Coffee  

8:30 - 10:15 AM - Session 9  
Sterilizing Filtration – Principles  

10:15 - 10:30 AM - Break  

10:30 - 12:15 AM - Session 10  
Sterilizing Filtration – Application & Operation  

12:15 – 1:15 PM - Lunch  

1:15 - 3:00 PM - Session 11  
US Regulatory & Compendial Expectations  

3:00 - 3:15 PM - Break  

3:15 - 4:45 PM - Session 12  
EU Regulatory & Compendial Expectations  

4:45 PM – Sterilization Course Ends
### Aseptic Processing: Compliance and Technology Schedule

#### Day 1 – Thursday – 9/26

<table>
<thead>
<tr>
<th>Time</th>
<th>Session/Activity</th>
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<tbody>
<tr>
<td>8:00 - 8:30 AM</td>
<td>Registration – Aseptic Course</td>
</tr>
<tr>
<td>8:30 – 10:00 AM</td>
<td>History of Aseptic Processing</td>
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<td></td>
<td>Aseptic Processing Technologies</td>
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<tr>
<td>10:00 – 10:30 AM</td>
<td>Break</td>
</tr>
<tr>
<td>10:30 AM – 12:15 PM</td>
<td>Session 2                                Sterility by Design</td>
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<tr>
<td>12:15 AM – 1:15 PM</td>
<td>Lunch</td>
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<tr>
<td>1:15 - 3:00 PM</td>
<td>Session 3 Facility / System Qualification</td>
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<td>3:00 - 3:15 PM</td>
<td>Break</td>
</tr>
<tr>
<td>3:15 – 5:00 PM</td>
<td>Session 4 Environmental Monitoring</td>
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<td>5:00 PM – Day 1 Ends</td>
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#### Day 2 – Friday – 9/27

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<thead>
<tr>
<th>Time</th>
<th>Session/Activity</th>
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<tbody>
<tr>
<td>7:30 - 8:00 AM</td>
<td>Morning Coffee</td>
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<tr>
<td>8:00 - 9:45 AM</td>
<td>Session 5 Interventions / Process Simulation</td>
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<td>9:45 - 10:00 AM</td>
<td>Break</td>
</tr>
<tr>
<td>10:00 – 11:45 AM</td>
<td>Session 6 Aseptic Processing Risk Assessment</td>
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<td>11:45 AM - 12:45 PM</td>
<td>Lunch</td>
</tr>
<tr>
<td>12:45 – 2:30 PM</td>
<td>Session 7 Aseptic Processing Regulation &amp; Compliance</td>
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<td>2:30 - 2:45 PM</td>
<td>Break</td>
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<tr>
<td>2:45 - 4:15 PM</td>
<td>Session 8 Review of Changes to EMA’s Annex 1 Future Directions in Aseptic Processing</td>
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<tr>
<td>4:15 PM – Aseptic Course Ends</td>
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Registration Form

1. Please print your name, address and company affiliation (use separate page for each attendee)

Mr. □ Ms. □ Dr. □  First Name  Last Name

Title  Company

Work Address

Country  Zip/Mail Code  City

Phone  E-mail

Course Attending

2. Sterilization Course Fee – Monday-Wednesday
☐ Early Registration Fee: $ 2,600  ☐ Normal Registration Fee: $ 2,900

Aseptic Processing Course Fee – Thursday-Friday
☐ Early Registration Fee: $ 1,800  ☐ Registration Fee: $ 2,000

Combined Sterilization & Aseptic Processing Course Fee – Monday-Friday
☐ Early Registration Fee: $ 4,100  ☐ Registration Fee: $ 4,600

Early Registration – Payment or PO # must be received no later than 45 days before the start of each course – August 9, 2019

Group Discount - Three or more attendees from same firm receive 10% discount on all registration for the same course.

3. Payment & Registration - Please make a copy of this page, and send the completed form along with your payment. You will not be registered, unless payment or purchase order is received with your completed registration form.

Please send all correspondence to:

Agalloco & Associates Inc., PO Box 899, Belle Mead, NJ 08502-0899 or jagalloco@aol.com